Remarks/Arguments:

The specification is amended, hereby, to insert the priority claim under §120 (prior non-provisional application). It is noted that the §120 priority claim was included in the transmittal of the subject (continuation) application.

Pursuant to the Office Action, in view of the foregoing amendment to the specification, the requirements for being accorded benefit of both the §120 (domestic) and §119 (foreign) priorities—as claimed—are satisfied. Request is made that the Examiner mark the next Office Action, accordingly, *i.a.*, to acknowledge the claim to §119 priority and receipt of the certified copy.

Claims 19-22, previously presented, are pending.

Claims 1-18 are canceled, without prejudice or disclaimer.

Claims 19-22 were rejected under 35 USC 112, 2nd ¶, for allegedly being indefinite. Reconsideration is requested.

The correct test for indefinite claim language is whether one of ordinary skill in the art would understand the meaning of subject matter defined by the language at issue. *In re Kroekel*, 183 USPQ 610 (CCPA 1974). Applying this test demonstrates that the language at issue satisfies the requirements of 35 USC 112, ¶2.

The term "*standardized*" will be immediately understood by the skilled person reading the specification. While claims are to be given their broadest reasonable interpretation during prosecution, the definition of a claim limitation given by the Examiner cannot be different than would be given by one of ordinary skill in the art. *In re Cortright*, 49 USPQ2d 1464 (Fed. Cir.

1999). For example, at page 3, second paragraph, and the paragraph bridging pages 3 and 4, the subject application teaches:

> One of the objects of the invention is, accordingly, assuring a smooth and reproducible procedure, ruling out the possibility of error due to abnormal reactions, and pointing out a way that allows results with the same test material to be compared when blood is used as the biological system for testing. It is intended that repeated tests at various sites can be standardized and made possible at various times. . . .
>
> Use of deep-frozen blood or a preparation containing such blood makes it possible to have available, at any time, as a biological system, blood which has been previously tested and so is free of abnormal reactions. At the minimum it can be standardized, and then used as a standard reagent.

Moreover, on page 9, first paragraph, the subject application teaches:

> Due to deep-frozen preservation it is possible to use the same blood repeatedly at different times and places. Abnormal blood reactions can be recognized in appropriate preliminary tests and the corresponding material can be removed. Standard values for the particular lot of blood can be determined in advance under standardized conditions.

Thus, it becomes readily evident from the teachings of the subject application that (1) the meaning of "*standardized blood*" is the whole blood itself, wherein any standardization can be carried out in a general sense, as long as it is the same for the tests and comparative tests. Therefore, (2) depending on the test various standard values can be determined in order to make the "*blood unit dose*" "*standardized*". The PTO must use the definition of a claim limitation given in the specification. *In re Zletz,* 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

> The purpose of the claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification.

S3 Inc. v. nVIDIA Corp., 59 USPQ2d 1745, 1748 (Fed. Cir. 2001).

Therefore, even if the term "*standardized*" may be considered broad it is not indefinite as several suitable standardizations can be carried out known to the skilled person for the respective tests. Claim "breadth is not to be equated with indefiniteness." *In re Miller*, 169 USPQ 597, 600 (CCPA 1970).

Furthermore, and with all due respect, the meaning of "*standardized blood unit dose*" appears to be understood by the PTO, in view of its being allegedly found in the cited prior art. The Office Action, page 7, lines 6-7, alleges that Rubenstein

> teach[es] thawing of the units for experimantal work thereby teaching a standardized blood unit dose, just as required by the claims.

Similarly, on page 9, line 3, "a standardized blood unit dose is taught" is allegedly by Kaye. Still further, on page 11, line 3, "the bags" in the cited Vora allegedly "provide a plurality of standardized blood unit dose[s], just as required by the claims." Since the PTO understands the meaning of "standardized blood unit dose" well enough to (allegedly) find it in the cited prior art, the claim term should not be considered indefinite, under §112, ¶2.

Claims 19-22 were rejected under 35 USC 102(b) as allegedly anticipated by each of Rubinstein, Kaye, and Vora. Reconsideration of the rejections is requested, since none of the cited references anticipates any of the rejected claims.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed.

Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Rubinstein discloses the processing and cryopreservation of placental/umbilical cord blood for unrelated bone marrow reconstitution. The object of Rubinstein ("*DISCUSSION*" on page 10121, last paragraph) is to provide smaller blood units and, so, provide advantages of convenience, cost, and efficiency—particularly with respect to the reduction of storage space. As set forth in to the abstract of Rubinstein (page 10119, lines 8-11):

> The large volume of unprocessed units, consisting mostly of red blood cells, plasma, and cryopreservation medium, poses a serious difficulty in this effort because storage space in liquid nitrogen is limited and costly.

Thus, Rubinstein teaches reducing the volume of blood (PCB) units by eliminating red-blood-cell bulk and plasma. As further taught by Rubinstein (page 10120, left hand side column):

> Reduction of PCB Bulk: Preparation of Leukocyte Concentrates (Lcs) . . . A leukocyte-rich supernatant is then separated by centrifuging the PCB/HES mixture in the original collection blood bag.

Still further, Rubinstein teaches (page 10121, right hand side column, final paragraph) (emphasis added):

> Reducing the volume of the PCB units by eliminating red blood cell, bulk and plasma offers pragmatic advantages of convenience, cost, and efficiency, compared with current alternatives.

These (and other) passages of Rubinstein make it readily apparent that *no whole blood* is used at all.

As opposed to Rubinstein, "using . . . whole blood" is an expressly recited feature (limitation) of the presently claimed invention. Moreover, it is critically important for obtaining reliable test results. In fact, the bulk-reduced (non-whole) blood disclosed in Rubinstein is not suitable in the presently claimed testing method. Therefore, a limitation on the rejected claims being absent from Rubinstein, the alleged anticipation is negated. *Kolster Speedsteel AB, supra.* Withdrawal of the §102(b) rejection based on Rubinstein appears to be in order.

Concerning the §102(b) rejection based on Kaye, the reference describes a novel method for the storage and preservation of whole blood samples, as a source of patient DNA for use in screening for immunodeficiency virus (HIV) type-I by polymerase chain reaction (PCR). As taught in Kaye (page 218, second paragraph) (emphasis added):

> We present here a method of storage and preservation of whole blood samples in a glycerol/gelatin based medium such that samples may be stored frozen after sampling and DNA suitable for use in PCR extracted up to 3 months later.

Further attention is directed Kaye, at 2nd and 3rd paragraphs, page 219, under the heading *"DNA extraction from Glycigel-preserved samples—method A/B"*.

As readily evident from the aforesaid passages, the testing method and preservation described in Kaye does not use whole blood at all; the reference describes merely "the storage and preservation of whole blood." Just as with Rubinstein, there is no test method described in Kaye using whole blood for detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against a material or object, as there is according to the presently claimed invention. The "absence"

of the "whole blood" limitation from Kaye "negates anticipation" of the present claims. *Kolster Speedsteel AB,* 230 USPQ at 84. Withdrawal of the §102(b) rejection based on Kaye appears to be in order.

Concerning the §102(b) rejection based on Vora the reference discloses a method and additives for improving the quality and shelf life of stored blood. However, contrary to the PTO allegation, Vora does not disclose a method "using . . . thawed cryopreserved . . . whole blood" in a method to test a material or object for an immunofunctional, toxic, or modulatory blood reaction.

Vora teaches (column 8, lines 1-4):

> A screening procedure is used to effectively test the efficacy of a number of compounds (almost all of which are physiological), that may be used as inhibitors of PK during blood banking.

Vora further teaches (column 8, lines 31-32) (emphasis added)

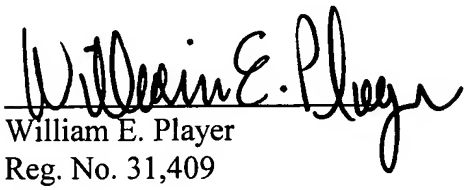
> The mixture of whole blood or red blood cells, anticoagulant and the preserving compound(s) is then stored at temperatures below 10°C, preferably at a temperature within the range of from about 1°C to about 6°C or lower with cryopreservative agents, e.g. glycerol.

Accordingly, while Vora discloses (1) using a whole-blood sample in a testing method and (2) cryopreservation of this same whole-blood sample, the sample is cryopreserved only after using it in the testing method. Vora does not disclose "using . . . a thawed cryopreserved . . . whole blood" sample, as recited in the present claims. Therefore, the "absence" of a claim limitation from Vora "negates anticipation" of the present claims by the reference. *Kolster Speedsteel AB*, 230 USPQ at 84. Withdrawal of the §102(b) rejection based on Vora appears to be in order.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 
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